

## **Preferred Drug List Committee Meeting**

### **Meeting Minutes, Open Session**

September 13, 2017 10:00 a.m.

DXC Technologies-Capital Room, 6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619

#### **Board Members Present:**

Taylor Gill, Pharm. D., BCPS, AAHIVP (Interim Chair)  
Donna Sweet, M.D., MACP (Chair) (Phone)

Robert Haneke, Pharm.D. (Phone)  
Wayne Wallace, M.D.

Megan Hedden, Pharm.D.

#### **Board Members Absent:**

Raymond Magee, M.D.

Emily Prohaska, Pharm.D., BCACP

#### **KDHE-DHCF Staff:**

Annette Grant, RPh

Robert Handke, Pharm.D.

Carol Arace, Sr. Admin. Asst.

#### **HP Staff Present:**

Karen Kluczykowski, RPh,

Nancy Perry, R.N.

Ellen McCaffrey, BSN, MSN

#### **HID Staff Present:**

Taylor DeRuiter, PharmD (Phone)

#### **MCOs Present:**

Jennifer Murff-United Healthcare

Angie Zhou-Sunflower

Lisa Todd-Amerigroup

#### **Public Attendees:**

Melena Basil, Abbvie; Jim Baumann, Pfizer; Blake Boretsky, Genentech; Rick Frost, Novo Nordisk; Brent Hildebrand, Gilead; Laura Hill, Abbvie; Cassandra Johnson, Purdue; Rick Keglen, Otsuka; Phil King, Pfizer; Scott Maurice, BI; Julie McDavitt, BI; Michele Puyear, Gilead; Brian Rose, Gilead; Susan Zalenski, J&J

Item	Facilitator (s)	Notes
<b>I. Call to Order</b>	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Dr. Gill called the September 13, 2017 PDL Committee meeting to order at 10:04am.
<b>I. Call to Order</b> <b>A. Announcements</b>	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Ms. Grant reminded everyone about the possible towing if anyone has parked south of the building. Dr. Gill notified the attendees about public comment with the length of time to make a public comment being five minutes. She also requested that if anyone wishes to make a public comment, they must fill out and turn in to her the Conflict of Interest form prior to speaking.
<b>II. Old Business</b> <b>A. Review and Approval of June 21, 2017 Minutes</b>	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	The draft minutes from the June 21, 2017 meeting were reviewed & approved as written. Dr. Sweet moved to approve the minutes. Dr. Wallace seconded the motion. The motion carried unanimously and the minutes were approved as written.
<b>II. Old Business</b> <b>B. PDL Organization - Dual Class Drug Placement</b> i. Proposed Amendment • Justification provided by the state ii. Public Comment iii. Committee Discussion/Recommendations	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	<b>Background:</b> Ms. Grant explained how placing a drug into the first class it's applicable to and not into any subsequent classes is beneficial to both the State and the Providers that are looking for the drug on the Kansas Preferred Drug List through an index that has been added. The proposal before the Committee is that when they add an agent, to add it to only one class. The class that it is most applicable to.  <b>Public Comment:</b> A public attended enquired as to when a combination class would be considered; to which Ms. Grant noted there would need to be significant competition of enough of those drugs with that combination to allow creating a class of its own.  <b>Committee Discussion:</b> Agents would be placed in the most applicable class by the most logical place a provider would look for that particular agent.  Dr. Wallace and Dr. Sweet moved to approve the proposal. Dr. Haneke seconded the motion.  The motion carried unanimously.

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<p><b>III. New Business</b></p> <p><b>A. Fluorouracil Agents – Topical – New Class: (Efudex, Tolak, Carac, Fluoroplex)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b> The medications in this class are indicated to treat Actinic or solar keratosis (pre-cancerous patches of thick, scaly, or crusty skin usually accompanied by abnormal pigmentation, etc.) when surgery has been deemed impractical. Carac cream was originally approved by the FDA 10/27/2000. The active ingredient is fluorouracil, which interferes with DNA synthesis and therefore elicits cell death of rapidly dividing skin cells. Efudex, Tolak, Carac, and Fluoroplex are the proposed new agents for this class. These products differ slightly in their strength, but all contain the same active drug molecule. Included for the board are package inserts and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Committee Discussion:</b></p> <p>Dr. Wallace moved to approve. Dr. Sweet seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>B. Rosacea Agents- Topical- New Class: (Finacea, Mirvaso, Soolantra, Rhofade, Metrocream, Metrogel, MetroLotion, Noritate, Rosadan)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b> The medications in this class are indicated for the treatment of rosacea. The mechanisms of these agents are to exhibit antimicrobial effects or to elicit vasoconstriction, which reduces erythema induced discoloration of the skin. The class consists of multiple metronidazole (Flagyl) dosage forms. Included for the board are package inserts and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Committee Discussion:</b></p> <p>Dr. Sweet moved to approve. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>

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<p><b>III. New Business</b>  <b>C. Hepatitis C</b>  <b>Retreatment- New</b>  <b>Class: (Vosevi,</b>  <b>Mavyret)</b></p> <p>i. Public Comment  ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill,</i>  <i>Pharm. D., BCPS,</i>  <i>AAHIVP</i></p>	<p><b>Background:</b>  The medications in this class are indicated for the treatment of refractory hepatitis C infections. The first agent proposed for this class is Vosevi, which is indicated for use in patients with a genotype 1-6 infection and had previously failed a regimen containing an NS5A inhibitor; or in patients with a genotype 1a or 3 infections and had previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. Vosevi is a combination drug that has activity against viral NS5B RNA polymerase, HCV NS5A replication protein, and NS3/4A proteases. In doing so, Vosevi can be utilized when other Direct Acting Antiviral drugs have failed to elicit complete eradication of the hepatitis C virus. Mavyret is indicated in retreatment in HCV 1 infections previously treated with an HCV NS5A inhibitor or an NS3/4A protease inhibitor but not both. Included for the board is a package insert and a class comparison chart.</p> <p><b>Public Comment:</b>  Michele Puyear with Gilead spoke on behalf of Vosevi. Laura Hill with Abbvie spoke on behalf of Mavyret for this class as well as Agenda Item.</p> <p><b>Committee Discussion:</b>  Dr. Sweet recused.</p> <p>Dr. Wallace moved to approve.  Dr. Haneke seconded the motion.  Dr. Sweet abstained.</p> <p>The motion carried.</p>
<p><b>III. New Business</b>  <b>D. Glucocorticoids- High</b>  <b>Potency Topical- New</b>  <b>Class: (Clobex, Clobex</b>  <b>Spray, Cordran,</b>  <b>Cormax Scalp</b>  <b>Application, Diprolene,</b>  <b>Diprolene AF, Olux,</b>  <b>Olux-E, Psorcon,</b>  <b>Temovate, Temovate E,</b>  <b>Topicort, Vanos,</b></p>	<p><i>Taylor Gill,</i>  <i>Pharm. D., BCPS,</i>  <i>AAHIVP</i></p>	<p><b>Background:</b>  Differentiate between the High, Intermediate, and Low Potency of these topical agents.</p> <p><b>Public Comment:</b>  None.</p> <p><b>Committee Discussion:</b>  Concern was noted of the duplications of agents within the three classes. Committee members asked that the duplicate items be removed and brought back next time for consideration. Duplications of Cordran, Elocon, Nolix, and Fluocinolone Body &amp; Scalp were removed.</p> <p>Dr. Sweet moved to approve as amended.</p>

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<p><b>Elocon, Halog, Sernivo, Clobetasol Propionate E, ApexiCon E, Clodan, Ultravate)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>		<p>Dr. Wallace seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>E. Glucocorticoids- Intermediate Potency Topical- New Class: (Cloderm, Cutivate, Luxiq, Cordran, Elocon, Kenalog, Synalar, Westcort, Capex, Dermatop, DesOwen, Locoid, Locoid LipoCream, Pandel, Nolix, Triderm, Dermasorb TA, Trianex, Oralone, Dermazone, Tridesilon, LoKara)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b> Differentiate between the High, Intermediate, and Low Potency of these topical agents.</p> <p><b>Public Comment:</b> None.</p> <p><b>Committee Discussion:</b> Concern was noted of the duplications of agents within the three classes. Committee members asked that the duplicate items be removed and brought back next time for consideration. Duplications of Cordran, Elocon, Nolix, and Fluocinolone Body &amp; Scalp were removed.</p> <p>Dr. Sweet moved to approve as amended. Dr. Wallace seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>F. Glucocorticoids- Mild Potency Topical - New Class: (Aclovate, Derma-Smooth/FS</b></p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b> Differentiate between the High, Intermediate, and Mild Potency of these topical agents.</p> <p><b>Public Comment:</b> None.</p>

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<p><b>Body &amp; Scalp, Fluocinolone Body and Scalp, Desonate, Verdeso, Ala-Cort, First-Hydrocortisone, Dermasorb HC, Pediaderm HC, Ala Scalp, NuCort, Texacort)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>		<p><b>Committee Discussion:</b></p> <p>Concern was noted of the duplications of agents within the three classes. Committee members asked that the duplicate items be removed and brought back next time for consideration. Duplications of Cordran, Elocon, Nolix, and Fluocinolone Body &amp; Scalp were removed.</p> <p>Dr. Sweet moved to approve as amended. Dr. Wallace seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>G. Hepatitis C Antiviral Agents- Class Review, New Agent: Mavyret®</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b></p> <p>Request to add the new agent Mavyret to this class.</p> <p><b>Public Comment:</b></p> <p>Laura Hill with Abbvie spoke on behalf of Mavyret</p> <p><b>Committee Discussion:</b></p> <p>Dr. Sweet recused.</p> <p>Dr. Hedden moved to approve. Dr. Wallace seconded the motion.</p> <p>The motion carried.</p>
<p><b>III. New Business</b></p> <p><b>H. Androgenic Agents – Class Rename &amp; New Agents: (Depo-Testosterone, Striant, Testred, First-Testosterone MC,</b></p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b></p> <p>The androgen class was last reviewed in March, 2016 and incorporated only topical testosterone products, but this class review proposition extends to incorporate all oral, IM, and topical agents. In this way, this class will comprehensively address all dosage forms of androgen agents used for hypogonadism, hormone replacement and suppression. Included for the board are package inserts and a class comparison chart.</p> <p><b>Public Comment:</b></p>

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<p><b>Natesto, Aveed, Androxy, Oxandrin, Methitest, Android)</b></p> <p>iii. Public Comment</p> <p>iv. Committee Discussion/Recommendations</p>		<p>None.</p> <p><b>Committee Discussion:</b></p> <p>Dr. Wallace moved to approve. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>I. Immunomodulation Agents- Plaque Psoriasis- Class Review, New Agent: (Tremfya)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b></p> <p>The immunomodulation agent class for plaque psoriasis was approved for a name change in early 2017. This proposition requests for the addition of another agent indicated for the treatment of plaque psoriasis. Tremfya is a monoclonal antibody that reduces downstream interleukin production through the binding of IL-23, which inhibits further release of pro-inflammatory agents. Included for the board's consideration is a package insert and a class comparison chart.</p> <p><b>Public Comment:</b></p> <p>None.</p> <p><b>Committee Discussion:</b></p> <p>Dr. Haneke moved to approve. Dr. Hedden seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>J. Immunomodulation Agents- Psoriatic Arthritis- Class Review, New Agent : (Orencia)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b></p> <p>The immunomodulation agent class for plaque psoriasis was approved for a name change in early 2017. This proposition requests for the addition of another agent indicated for the treatment of psoriatic arthritis. Orencia exhibits immunosuppression by inhibiting T-cell activation, and accomplishes this by interfering with the connection between T-cell's CD28 receptor and antigen presenting cells. Included for the board's consideration is a package insert and a class comparison chart.</p> <p><b>Public Comment:</b></p> <p>None.</p>

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		<p><b>Committee Discussion:</b></p> <p>Dr. Wallace moved to approve. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>K. Hereditary Angioedema Agents- Class Review, New Agent: (Haegarda)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b> The Hereditary Angioedema Agents Class was last reviewed as a new class in June, 2017. Berinert, Cinryze, Firazyr, Kalbitor, and Ruconest were approved agents in this class. This proposition requests for the addition of another agent, Haegarda, to this class of agents. This agent rectifies a genetic defect of the C1-esterase inhibitor, which results in high levels of bradykinin and consequently fluid to leak in surrounding tissue. Haegarda replaces the deficient C1-esterase inhibitor and interrupts the pathway resulting in upregulated bradykinin. Included for the board's consideration are package inserts and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Committee Discussion:</b></p> <p>Dr. Wallace moved to approve. Dr. Hedden seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>L. SGLT2 Inhibitors- Class Review, New Agent: (Xigduo XR)</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b> The SGLT2 inhibitors class was last modified in June, 2017 to include the medication Qtern. This class of drugs is an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. This proposition requests for the addition of another agent, Xigduo XR, to this class of medications. Xigduo XR is a combination product that includes a SGLT2 inhibitor, dapagliflozin, and metformin. Included for the board's consideration is the package insert and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p>



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		<p><b>Committee Discussion:</b></p> <p>All Committee members (per the Chair) moved to approve. All Committee members (per the Chair) seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b>  <b>M. Inhaled Corticosteroids-  Class Review- New  Agent: (QVAR  RediHaler)</b>  i. Public Comment  ii. Committee  Discussion/Recommend  ations</p>	<p><i>Taylor Gill,  Pharm. D., BCPS,  AAHIVP</i></p>	<p><b>Background:</b>  The inhaled corticosteroid class was developed in February, 2005 and last reviewed in June, 2017. The June, 2017 review meeting considered Armonair RespiClick for inclusion. Today, Qvar RediHaler is the one agent being presented for inclusion. Qvar RediHaler is an HFA propelled inhaler indicated for the prophylactic treatment of asthma in patients 4 years of age and older. Package insert and a class comparison chart are included for the board.</p> <p><b>Public Comment:</b>  None.</p> <p><b>Committee Discussion:</b></p> <p>Dr. Sweet moved to approve.  Dr. Hedden seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b>  <b>N. Anaphylaxis Agents-  Class Review- New  Agent: (Symjepi)</b>  i. Public Comment  ii. Committee  Discussion/Recommend  ations</p>	<p><i>Taylor Gill,  Pharm. D., BCPS,  AAHIVP.</i></p>	<p><b>Background:</b>  This class of medications is used for the emergency treatment of allergic reactions (type 1), which includes anaphylactic reactions in response to insect stings or bites, allergen immunotherapy, foods, drugs, diagnostic testing substances, allergens, etc. The last medication reviewed for this class was Auvi-Q. A package insert and a class comparison chart is provided for the board.</p> <p><b>Public Comment:</b>  None.</p> <p><b>Committee Discussion:</b></p>

Item	Facilitator (s)	Notes
		<p>Dr. Haneke moved to approve. Dr. Sweet seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>III. New Business</b></p> <p><b>O. Pre-approval for drug molecule dose form, dose device, IR/ER of current PDL drug</b></p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p><b>Background:</b> Ms. Grant noted that ‘strength’ should also be in the title. The request to the Committee is to allow the State to have pre approval ability to add already existing name brand agents that are considered new to their classes when it is only a change of form, strength, or IR/ER that is different instead of bringing the class back each time for approval to add the new form of an already existing agent. The Brand name not the Generic name.</p> <p><b>Public Comment:</b> Public concern over the State not having to go through rules and regulations. Also noted was the risk to the PDL Committee when they do not review agent/s before addition to the preferred drug list. If there are clinical issues between agents, the Committee may not know an agent was added since it did not go before the Committee prior to addition to the list. Another attendee was concerned with no public input when agent/s are added without prior knowledge. Request to have this process written and provided to the public for better understanding and intentions. The Committee noted that all this information would be in the minutes.</p> <p><b>Committee Discussion:</b> Ms. Grant noted that if agents are found to work for other indications, those would be brought back before the Committee for consideration. The XR/IR does give concern. Ms. Grant agreed to agents per brand name. If there is an agent that is offered under two different brand names, it would be brought to the Committee for discussion. Dr. Gill suggested that any agents pre-approved by the State should be listed on each PDL Agenda under ‘Old Business’ as ‘Consent Agenda Items’ and list those agents in an ‘Appendix A’. ‘Appendix A’ would be a list of the changes/additions the State has made. This way, should there be an issue, the Committee could pull out any agent in question and vote on it separately in front of the entire Committee and would be available to the public for comment.</p> <p>The motion before the Committee is: ‘Pre-approval for drug molecule dose form, dose device, IR/ER, and strength of a current PDL drug with the State providing ‘Consent Agenda Items’ with a list of agents, under ‘Old Business’ as a report to the Committee at each PDL meeting.’</p> <p>Dr. Haneke moved to approve as amended.</p>

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		<p>Dr. Sweet seconded the motion as amended.</p> <p>The motion carried as amended unanimously.</p>
<b>III. New Business</b> <b>P. Review of Previous Placement- Removal of Qtern from DPP-4 Inhibitor Class</b> <ul style="list-style-type: none"> <li>i. See decision on II B Old Business</li> <li>ii. Public Comment</li> <li>iii. Committee Discussion/Recommendations</li> </ul>	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	<p><b>Background:</b> Request to remove an agent from the DPP-4 class that was discussed and voted on at the June 2017 meeting. The request is to remove Qtern and Glyxambi (Agenda Item Q) from the second class they were put in and keep them in their original class (SGLT-2) to be consistent with dual agent classes.</p> <p><b>Public Comment:</b>  Julie McDavitt with BI brought up concerns with the prior authorization criteria in the SGLT-2 class. The request was made to have the criteria read ‘either’ agent instead of possibly having folks go through the step process again. In response, Ms. Grant noted that criteria is something that has to go before the Drug Utilization Review Board.</p> <p><b>Committee Discussion:</b></p> <p>Dr. Wallace moved to approve both Agenda Item P and Q.  Dr. Hedden seconded the motion.</p> <p>The motion carried unanimously.</p>
<b>III. New Business</b> <b>Q. Review of Previous Placement- Removal of Glyxambi from DPP-4 Inhibitor Class</b> <ul style="list-style-type: none"> <li>i. See decision on II B Old Business</li> <li>ii. Public Comment</li> <li>iii. Committee Discussion/Recommendations</li> </ul>	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	<p><b>Background:</b> Request to remove an agent from the DPP-4 class that was discussed and voted on at the June 2017 meeting. The request is to remove Qtern and Glyxambi (Agenda Item Q) from the second class they were put in and keep them in their original class (SGLT-2) to be consistent with dual agent classes.</p> <p><b>Public Comment:</b>  Julie McDavitt with BI brought up concerns with the prior authorization criteria in the SGLT-2 class. The request was made to have the criteria read ‘either’ agent instead of possibly having folks go through the step process again. In response, Ms. Grant noted that criteria is something that has to go before the Drug Utilization Review Board.</p> <p><b>Committee Discussion:</b></p> <p>Dr. Wallace moved to approve both Agenda Item P and Q.</p>

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		Dr. Hedden seconded the motion.  The motion carried unanimously.
<b>IV. Open Public Comment</b>	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	None.
<b>V. Adjourn</b>	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Dr. Wallace moved to adjourn. Dr. Sweet seconded the motion.  Dr. Gill adjourned the meeting at 10:57am.